REMARKS

In the Office Action of November 1, 2004, each of pending claims 11 through 21 are rejected under 35 U.S.C §103(a) as being obvious in light of United States Patent 6,167,605 to Morales ("Morales patent"). As was explained at the interview held on March 15, 2005, the present invention is neither taught nor suggested by the Morales patent. Reconsideration and allowance of the claims as amended are respectfully requested.

Applicants wish to thank Examiner Bui for his time, consideration, and helpful suggestions provided at the personal interview held on March 15, 2005. The following is a summary of the substance of the interview.

During the interview inventors Edward Cully and Michael Vonesh reviewed the prior art processes for compacting a self-expanding stent and stent-graft devices. As was explained, in order to compact a self-expanding implantable device, the device must be compressed and then, while maintained in the compacted dimension, constrained for subsequent release at an implantation site in a body.

Earlier balloon-expandable stent-devices were shown at the interview and it was explained that it is common to compact these devices using various crimping devices, such as the iris-based crimping device shown at the interview. Since these stent-devices are plastically deformable, they will retain essentially whatever compacted dimensions into which they are formed without the need for constraint. These devices can then be deployed in the body without constraint, with the device enlarged at the implantation site using a balloon or similar device to plastically deform the device into its final deployed dimensions.

As was explained, prior to the present invention, self-expanding devices were typically pulled through a smooth funnel (or smooth "tapered die") into a constraint (e.g., a catheter tube or constraining sleeve). This process worked well, but could lead to a number of problems. As was demonstrated at the interview, devices pulled through a smooth funnel tend to compact randomly. This was clearly shown at the interview with a helical stent-graft that was compacted within a semi-transparent tube. The stent-graft formed random folds within the tube, with the stent element folding over and under itself in a somewhat haphazard manner. As was explained, when a self-expanding device compacts in this random manner it tends to limit the extent of compaction that can be achieved, both because the device is not neatly folded (like stuffing a shirt into a suitcase versus neatly folding it in an organized manner) and haphazard compacting of the device can lead

to device damage if the device is compacted too tightly (since the points at which stent and graft cross-over occur within the constraint cannot be predicted and excessive constraint could cause abrasion of the device elements as they compact over or under each other). Additionally, the inventors determined that random compacting of a self-expanding stent also can increase the amount of force needed to compact the stent as well as increase the amount of force need to deploy the stent in those instances where the stent is pushed out of a catheter tube for deployment. Again, when increased compaction (and, where applicable, deployment) force is required, the extent of compaction may be limited by how much force the implantable device can safely withstand without damage in the compaction or deployment processes.

These problems were addressed by the present inventors by providing a "fluted funnel" through which self-expanding devices can be compacted. As was shown at the interview, the inventors have devised a number of tapered die devices with defined internal ridges (i.e., flutes) therein. By pulling a self-expanding device through such a fluted construct the self-expanding device will consistently fold in a pre-determined manner into uniform pleats. This process was demonstrated at the interview and a self-expanding stent-graft was shown compacted within a semi-transparent tube with uniform pleating of the device along its length.

This process provides self-expanding devices that are far more consistently and predictably compacted. It has been determined that this allows these devices to be safely and reliably compacted into smaller introductory profiles. As was explained, reduction in introductory profiles is strongly desired in the interventional medical procedures where smaller and smaller incisions for catheter introduction are always desired, and small profiles are required to reach more challenging treatment sites in the body.

Additionally, the present inventors determined that providing predictable compaction of the self-expanding devices also provides other benefits. For example, once the inventors demonstrated that a self-expanding stent could be repeatedly and predictably compacted into the same pleated pattern, they could then study other factors allowing for greater compaction efficiencies. As is explained in the present application, the inventors determined that a self-expanding device can be pulled through a series of funnels and "trained" to assume even smaller compacted dimensions. Although fluting is not required to gain all the benefits of such repeated pull-downs, the predictability of the uniform pleating allowed the inventors to accurately demonstrate the benefits of such a procedure. Moreover, the inventors have demonstrated that combining uniform pleating with repeated pull-downs can provide a very tightly compacted device.

The cited Morales patent was also discussed at the interview. As was explained, the Morales patent is directed to a collet device used to crimp a plastically deformable stent device onto a balloon for later deployment in a body. See, e.g., Abstract; col. 3, lines 41-47 ("...the segmented jaws at the collet end ... converge and close down on the stent. This closing action crimps the stent onto the balloon.").

At the interview the inventors showed a device very similar to Morales' crimper – a machine tool collet that has a number of segments that can be tightly closed around a piece to retain it in place (similar to the chuck used to retain drill bits on a hand drill). Applicants demonstrated at the interview that this device can be effectively used to compact a balloon-expandable stent into a compacted dimension. As was shown, similar to a drill chuck, Morales' device is designed to close down uniformly around the stent device so that it preferably forms a single compacted diameter following compaction. See Figure 6, element 58; col. 3, lines 49-54 ("...grooves are formed along the length of each jaw so that in their closed state, the grooves collectively form a cylindrical cavity the dimensions and shape of which match the crimped stent and contain the crimped stent and the catheter balloon when the segmented jaws have fully converged." (emphasis added)). Although for some applications Morales suggests that the jaws can be "profiled to vary diameter and contours along the length of the crimped stent," the patent contains no teaching or suggestion of apparatus to create a folded or pleated crimped stent. Cf. Col. 3, lines 29-31; col. 3, lines 54-56.

As was explained at the interview, Morales' process does not achieve any of the benefits of the present invention. First, this compaction method does not lend itself to compacting a self-expanding device since there is no way to retain a self-expanding device in its compacted dimensions following compaction in a collet-type fixture (that is, once a self-expanding device is compacted, it will immediately start to expand once the compaction force is removed). Nothing in the Morales patent teaches or suggests how to avoid such a result.

Second, and more importantly, the Morales patent employs a device with smooth inner walls to compact the balloon expandable device into a cylindrical (that is, non-pleated) form. See, e.g., Figure 6, element 58. The Morales patent neither teaches nor suggests that compacting a device with pleats would be in any way desirable. Moreover, Morales provides no teaching of how one would modify his crimping device to achieve uniform pleating of a self-expanding implantable device.

During the interview it was agreed that the method defined by claim 11 defines over the collet of the Morales patent when it is amended to define that the flutes and grooves of the

internally tapered die of the present invention cause the endoprosthesis to fold into uniform pleats. Nothing in the Morales patent or any of the other references of record in any way teaches or suggests a method of compacting a self-expanding endoprosthesis in this manner.

Additionally, the dependent claims further define the process of the present invention over the Morales patent, as well as the other references of record. As was explained above, one of the benefits discovered by using the fluted die of the present invention is that even greater compaction efficiencies can be achieved by pulling the self-expanding endoprosthesis through the fluted die, allowing it to expand, and then repeating the process. This process achieves improved compaction whether it is done through a single die twice or through different dies of different sizes. Morales teaches that his device can be used repeatedly on a plastically deformable stent to achieved a satisfactory crimped stent-balloon interface (see, e.g., col. 3, line 62 to col. 4, line 2), but he does not suggest that the stent should be enlarged between each application of his collet. Nowhere in the patent does Morales suggest that repeatedly pulling down a self-expanding device would achieve any benefits. In fact, it could be considered counterintuitive that a device could be better compacted if it is compacted once through a funnel, allowed to enlarge, and then compacted again through the same funnel. Dependent claims 12, 13, 14, and 21 define various inventive aspects of this "training" compaction process.

Also demonstrated at the interview was the use of tether lines used to pull the self-expanding device through the fluted funnel. As was shown, tether lines attached to the implantable device will self-align into the grooves in the funnel so that the device will automatically fold in the predetermined manner. There is no discussion in the Morales patent about the use of tether lines at all, much less how such tether lines might be used in conjunction with a fluted tapered die to create a pleated compacted device. Dependent claims 15, 16, 17, and 19 define various inventive aspects of the present invention as they relate to the use of such tether lines.

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For the foregoing reasons, neither the Morales patent nor any of the other references of record teach or suggest the present invention as it is now defined in the amended claims. Each of the claims of the present application is both new and non-obvious over all of the references of record. Reconsideration and allowance of the claims are respectfully requested. If any questions remain, applicants request a further interview prior to the next Office Action.

Respectfully submitted,

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